



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-P-5124]

Medical Devices; Exemption From Premarket Notification: Over-The-Counter Denture Repair Kits

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it has received a petition requesting exemption from the premarket notification requirements for over-the-counter (OTC) denture repair kits. These devices consist of material, such as a resin monomer system of powder and liquid glues, which is intended to be applied permanently to a denture to mend cracks or breaks. FDA is publishing this notice to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-P-5124 for "Medical Devices; Exemption From Premarket Notification: OTC Denture Repair Kits." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about

FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527.

#### SUPPLEMENTARY INFORMATION:

##### I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94-295)), as amended by the Safe Medical Devices Act of 1990 (Pub. L. 101-629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III

(premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105-115). Section 206 of FDAMA, in part, added new section 510(m) to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the *Federal Register* a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be

required for these devices upon the date of publication of the list in the *Federal Register*. FDA published that list in the *Federal Register* of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that, 1 day after the date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section, as amended by the 21st Century Cures Act (Pub. L. 114-255), requires FDA to publish in the *Federal Register* a notice of intent to exempt a device, or of the petition, and to provide a 60-day comment period. Within 120 days of publication of this document, FDA must publish in the *Federal Register* its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

## II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff." That guidance is available through the internet at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf> or by sending an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

### III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Paul Hyman, Hyman, Phelps & McNamara, PC, 700 13th St., NW, Suite 1200, Washington, DC 20005-5929, for OTC denture repair kits, classified under 21 CFR 872.3570.

### IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120.

Dated: November 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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